

8. the sale, purchase, or trade of blood and blood components intended for transfusion; or

9. the sale of legend drugs by retail pharmacies to licensed practitioners for office use where the annual dollar volume of legend drugs sold to licensed practitioners does not exceed five percent of the dollar volume of that retail pharmacy's annual legend drug sales.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 35:1537 (August 2009), amended LR 36:321 (February 2010).

John Liggio
Executive Director

1002#040

RULE

Department of Health and Hospitals Board of Wholesale Drug Distributors

Wholesale Drug or Device Distributors (LAC 46:XCI.301 and 311)

The Louisiana Board of Wholesale Drug Distributors has amended LAC 46:XCI.301 and 311 in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq. and R.S. 37:3467 et seq., of the Louisiana Board of Wholesale Drug Distributors Practice Act. These Rule amendments will support the board's ability to license entities and regulate the wholesale distribution of legend drugs and devices into and within the state of Louisiana in its effort to safeguard the life and health of its citizens and promote the public welfare. The amendments to the Rule are set forth below.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part XCI. Wholesale Drug Distributors

Chapter 3. Wholesale Drug or Device Distributors

§301. Licensing, Renewal and Reinstatement Requirements

A. - G.3. ...

H. An initial application for a new license is valid for 180 days after receipt by the board and must be completed within this time frame.

1. If the application is not completed, the application becomes void and any application fee(s) paid is forfeited by the applicant and is non-refundable.

2. After the 180 days have expired, a new application for a license will be required to be submitted by the applicant to include payment of another license application fee.

I. Requests for voluntary cancellation of a license made by a licensee must be made in writing and must include information such as, but not limited to, the date the request is effective and the reason for the voluntary cancellation of the license.

1. If the request for voluntary cancellation is made before the license has expired, the original unexpired license certificate must be returned to the board and no refund of any portion of the license fee(s) paid will be made by the board.

J. If a licensed in-state wholesale drug or device distributor has an additional off-site storage facility, the off-site storage facility may operate under the current wholesale drug or device distribution license held by the licensee as long as the off-site storage facility is in compliance with §309.A.1 of these regulations and has temperature monitoring and an alarm system and the off-site storage facility does not physically receive or distribute legend drugs or devices from its location.

K. A license shall not be issued by the board for any wholesale drug or device distributor to operate from or out of a dwelling, building, or property zoned as residential.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:382 (April 1992), amended LR 29:1480 (August 2003), LR 32:396 (March 2006), LR 34:875 (May 2008), LR 35:1538 (August 2009), LR 36:322 (February 2010).

§311. Drug or Device Distribution Recordkeeping

A. - E. ...

F. Wholesale drug or device distributors physically located and conducting operations in Louisiana:

1. shall not purchase or receive drugs or devices from other than wholesale drug distributors licensed by the board to ship or sell in or into Louisiana; and

2. shall notify the board of any wholesalers not licensed by this Board shipping in or into Louisiana or selling or offering to sell in or into Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:383 (April 1992), amended LR 29:1480 (August 2003), LR 32:399 (March 2006), LR 34:875 (May 2008), LR 36:322 (February 2010).

John Liggio
Executive Director

1002#042

RULE

Department of Health and Hospitals Bureau of Health Services Financing

Facility Need Review—Adult Day Health Care Providers (LAC 48:I.12501, 12503, 12505 and 12525)

The Department of Health and Hospitals, Bureau of Health Services Financing has amended LAC 48:I.12501, §12503, §12505 and to adopt §12525 in the Medical Assistance Program as authorized by R.S. 36:254 and R.S. 40:2116. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950, et seq.

Title 48
PUBLIC HEALTH—GENERAL
Part 1. General Administration
Subpart 5. Health Planning

Chapter 125. Facility Need Review

Subchapter A. General Provisions

§12501. Definitions

A. Definitions. When used in this Chapter the following terms and phrases shall have the following meanings unless the context requires otherwise.

Adult Day Health Care (ADHC)—provides services five or more hours a day (not to exceed five days per week) for medical, nursing, social, care management, and personal care needs to adults who are functionally impaired.

Adult Day Health Care Provider—any place owned or operated for profit or nonprofit by a person, society, agency, corporation, institution, or any other group, wherein two or more functionally impaired adults who are not related to the owner or operator of such agency are provided with adult day health care services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2116.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:806 (August 1995), amended LR 25:1250 (July 1999), amended LR 28:2190 (October 2002), amended LR 30:1023 (May 2004), amended LR 32:845 (May 2006), LR 34:2611 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:323 (February 2010).

§12503. General Information

A. - B. ...

C. The department will also conduct a FNR for the following provider types to determine if there is a need to license additional units, providers or facilities:

1. adult residential care providers or facilities;
2. home and community-based service providers, as defined under this Chapter; and
3. adult day health care providers.

D. - D.1.d. ...

E. No nursing facility, skilled nursing facility, or ICF-DD bed, nor provider units/beds shall be enrolled in the Title XIX Program unless the bed has been approved through the FNR Program. No adult residential care provider, home and community-based services provider or adult day health care provider may be licensed by the department unless the facility, unit or agency has been approved through the FNR Program.

F. - F.4. ...

G. Additional Grandfather Provision. An approval shall be deemed to have been granted under FNR without review for HCBS providers, ICFs-DD and ADHC providers that meet one of the following conditions:

1. HCBS providers which were licensed by January 31, 2009 or had a completed initial licensing application submitted to the department by June 30, 2008;
2. existing licensed ICFs-DD that are converting to the proposed Residential Options Waiver; or
3. ADHC providers who were licensed as of December 31, 2009 or who had a completed initial licensing application submitted to the department by December 31,

2009, or who are enrolled or will enroll in the Louisiana Medicaid Program solely as a Program for All-Inclusive Care for the Elderly provider.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2116.

HISTORICAL NOTE: Repealed and repromulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:808 (August 1995), amended LR 28:2190 (October 2002), LR 30:1483 (July 2004), LR 34:2612 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:323 (February 2010).

§12505. Application and Review Process

A. FNR applications shall be submitted to the Bureau of Health Services Financing, Health Standards Section, Facility Need Review Program. Application shall be submitted on the forms (on 8.5 inch by 11 inch paper) provided for that purpose, contain such information as the department may require, and be accompanied by a nonrefundable fee of \$10 per bed or unit for nursing facilities, ICFs-DD and adult residential care providers. The nonrefundable application fee for an HCBS provider (other than an adult residential care provider) and an ADHC provider shall be a flat fee of \$150. An original and three copies of the application are required for submission.

A.1. - B.3. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2116.

HISTORICAL NOTE: Repealed and repromulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:812 (August 1995), amended LR 34:2612 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:323 (February 2010).

Subchapter B. Determination of Bed, Unit, Facility or Agency Need

§12525. Adult Day Health Care Providers

A. No ADHC provider shall be licensed to operate unless the FNR Program has granted an approval for the issuance of an ADHC provider license. Once the FNR Program approval is granted, an ADHC provider is eligible to be licensed by the department, subject to meeting all of the requirements for licensure.

B. The service area for proposed or existing ADHC providers is the parish in which the ADHC provider is or will be licensed.

C. Determination of Need/Approval

1. The department will review the application to determine if there is a need for an additional ADHC provider in the geographic location for which the application is submitted.

2. The department shall grant FNR approval only if the FNR application, the data contained in the application, and other evidence effectively establishes the probability of serious, adverse consequences to recipients' ability to access adult day health care if the ADHC provider is not allowed to be licensed.

3. In reviewing the application, the department may consider, but is not limited to, evidence showing:

- a. the number of other ADHC providers in the same geographic location and parish servicing the same population; and
- b. allegations involving issues of access to health care and services.

4. The burden is on the applicant to provide data and evidence to effectively establish the probability of serious, adverse consequences to recipients' ability to access health care if the provider is not allowed to be licensed. The department shall not grant any FNR approvals if the application fails to provide such data and evidence.

D. Applications for approvals of licensed providers submitted under these provisions are bound to the description in the application with regard to the type of services proposed as well as to the site and location as defined in the application. FNR approval of licensed ADHC providers shall expire if these aspects of the application are altered or changed.

E. FNR approvals for licensed ADHC providers are non-transferrable and are limited to the location and the name of the original licensee.

1. An ADHC provider undergoing a change of location in the same parish in which it is licensed shall submit a written attestation of the change of location and the department shall re-issue the FNR approval with the name and new location. An ADHC provider undergoing a change of location outside of the parish in which it is licensed shall submit a new FNR application and fee and undergo the FNR approval process.

2. An ADHC provider undergoing a change of ownership shall submit a new application to the department's FNR Program. FNR approval for the new owner shall be granted upon submission of the new application and proof of the change of ownership, which shall show the seller's or transferor's intent to relinquish the FNR approval.

3. FNR approval of a licensed ADHC provider shall automatically expire if the ADHC provider moves or relocates, if the ADHC provider sells, transfers, or conveys ownership of the ADHC provider to another party or entity, or if the ADHC provider sells, transfers or conveys the FNR approval to another party, entity, or location, unless the ADHC provider has submitted application to and received approval from the FNR Program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2116.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:323 (February 2010).

Alan Levine
Secretary

1002#078

RULE

Department of Health and Hospitals Bureau of Health Services Financing and

Office for Citizens with Developmental Disabilities

Home and Community-Based Services Waivers Children's Choice Family Training Services (LAC 50:XXI.11303 and 12101)

The Department of Health and Hospitals, Bureau of Health Services Financing and the Office for Citizens with Developmental Disabilities has amended LAC

50:XXI.11303 and §12101 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950, et seq.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE Part XXI. Home and Community-Based Services Waivers

Subpart 9. Children's Choice

Chapter 113. Service

§11303. Service Definitions

A. - D.5. ...

E. Family training consists of formal instruction offered through training and education designed to assist the families of Children's Choice Waiver (CCW) participants in meeting the needs of their children.

1. The training must be conducted by professional organizations or practitioners and offer formal instruction that is relevant to the waiver participant's needs as identified in the plan of care.

2. Family training must be prior approved by the Bureau of Health Services Financing or its designee, the Office for Citizens with Developmental Disabilities, and incorporated into the approved plan of care.

3. For purposes of this service only, "family" is defined as unpaid persons who live with or provide care to the waiver participant, and may include a parent, stepparent, grandparent, sibling, legal guardian or foster family.

4. Payment for family training services includes coverage of registration and training fees associated with formal instruction in areas relevant to the participant's needs as identified in the plan of care. Payment is not available for the costs of travel, meals and overnight lodging to attend a training event or conference.

F. - F.2. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:1983 (September 2002), amended by the Department of Health and Hospitals, Office of the Secretary, Office for Citizens with Developmental Disabilities, LR 33:1871 (September 2007), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office for Citizens with Developmental Disabilities, LR 36:324 (February 2010).

§12101. Reimbursement Methodology

A. - B.1. ...

2. Family training shall be reimbursed at cost.

B.3. - B.4.j.iv. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:1987 (September 2002), LR 33:1872 (September 2007), amended by the Department of Health and Hospitals, Office for Citizens with Developmental Disabilities, LR 34:250 (February 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office for Citizens with Developmental Disabilities, LR 36:324 (February 2010).